

MODULA® SF

Modular Neck System

ADLER®
ORTHO

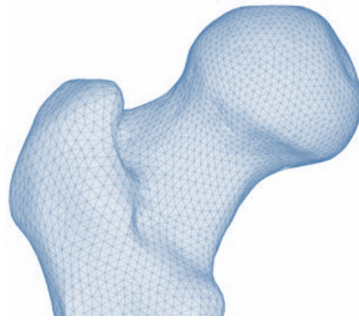


Universal Modular System

The importance of MODULARITY

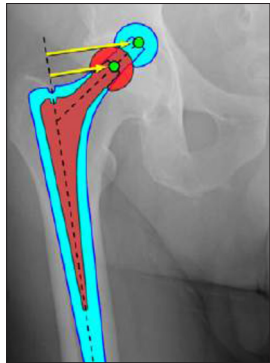
The main parameters of the human femur are:

- Neck Length
- Size of the diaphysis
- CCD Angle
- Offset
- Anteversion



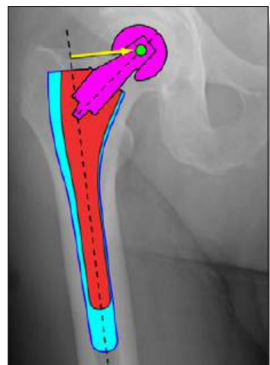
The proximal femoral anatomy has a great deal of variability. (1;2;3; 20)

There's no correlation between the diaphyseal size and the proximal femoral anatomy (1)



Monobloc stems

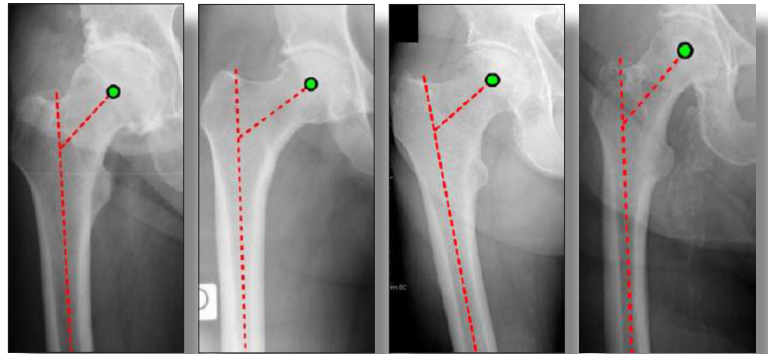
These stems are a compromise between dimensions which often vary in opposite ways.



Modular stems.

The stem is chosen according to the femoral shaft dimension. The necks are then selected based on the other parameters.

Anatomies which are difficult to reconstruct with monobloc stems.



Short Neck
Large Shaft
Low Offset

Long Neck
Thin Shaft
High Offset

Short Neck
Large Shaft
High Offset

Long Neck
Thin Shaft
Low Offset

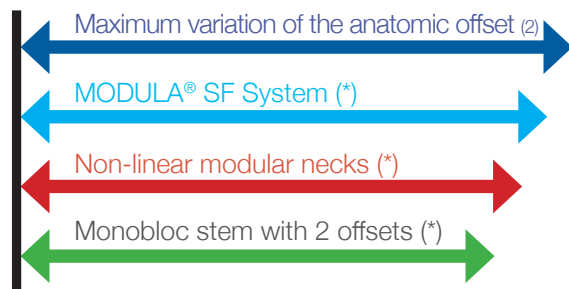
Monobloc stems, even with 2 offset options, cannot precisely reconstruct anatomic variables characterized by "non-standard" ratios between geometric parameters. (5;7)

The importance of the offset.

The human offset can vary between 27mm and 57mm. (2)

An incorrect offset reconstruction can cause:

- An increase of the risk of luxations (8)
- An increase of the mechanical stress on the implant (9)
- An increase of the Polyethylene wear (10)



The MODULA® SF system features an offset range between a minimum of 28mm and a maximum of 54mm.

MODULA® SF reproduces the anatomy more precisely.

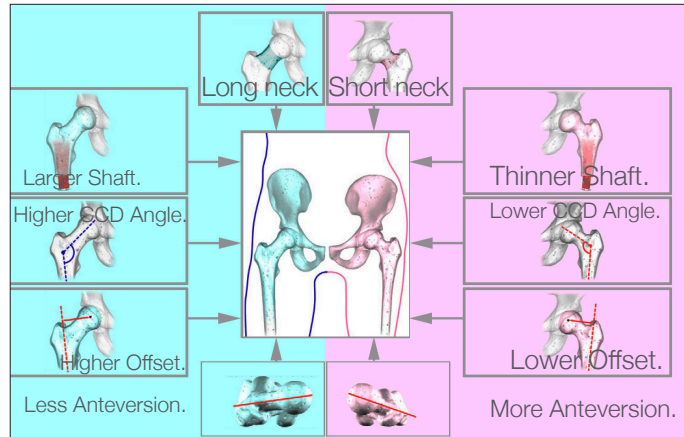
(*) Data available from Adler Ortho.

The ideal implant should be able to reproduce the human anatomy as faithfully as possible

Within the already large human variability, there are significant variations which are gender related (4,5,6)



- Larger Shaft.
- Higher CCD Angle.
- Longer Neck.
- Higher Offset.
- Less Anteversion.

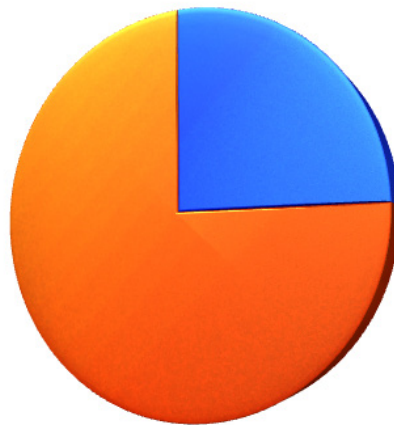


- Thinner Shaft.
- Lower CCD Angle.
- Shorter Neck.
- Lower Offset.
- More Anteversion.

The luxation problem

Luxations are the most common causes for revisions with an overall incidence between 1.5% and 3% (11)

The use of modular stems reduced the overall incidence of luxations to 0.7%, and it also halved the recurrence of this complication in women (women/men ratio 2:1) (5)



- Luxations
- Other causes

Luxations cause in average 25% of all revisions (12;13;14). Research shows that the women/men ratio for this complication is 4:1 (12).

Luxations have a higher incidence in women due to their higher physiological degree of anteversion:

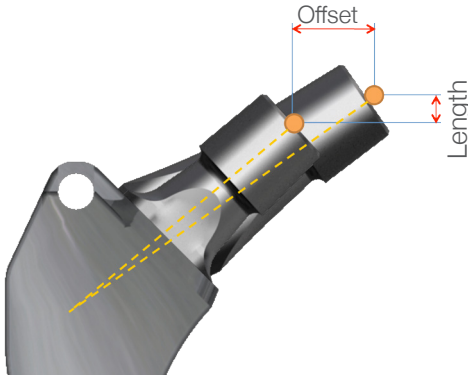
- Impossible to reconstruct with monobloc stems.
- Difficult to compensate with non-linear modular systems.

MODULA® SF is the true Universal Modular System.

The MODULA® SF System is linear.

Modular systems aren't all the same.
There are angular systems, that rely on pre-set angular variations.
The MODULA® SF system is linear, because it's based on pre-set spatial positions.

Angular Systems



When we try to correct a certain geometric parameter (e.g. the offset), we must also modify its complementary one (length)

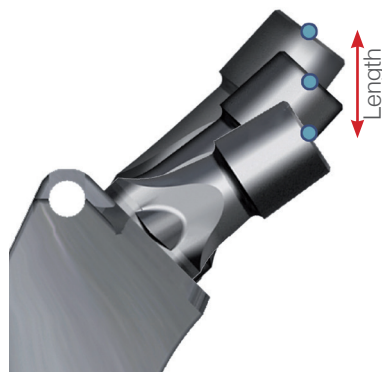
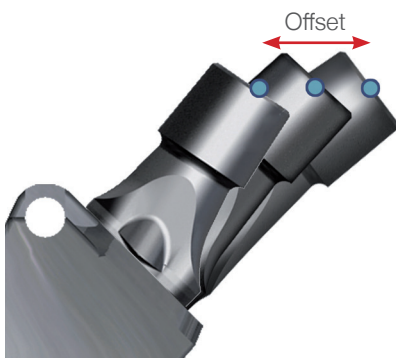


Version correction is also non-linear. Shorter necks have lower version than longer ones.

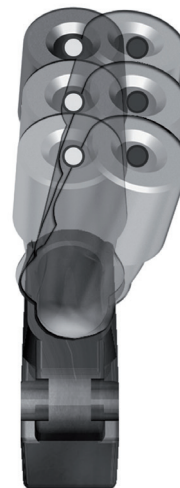
Anatomies with shorter necks and higher version degrees (mainly female patients) are not reconstructed correctly.

In angular systems the modification of one parameter affects the others.

The MODULA® SF System



The surgeon can freely adjust one parameter at the time, without affecting in any way the complementary parameter.



The version is the same for every neck length.

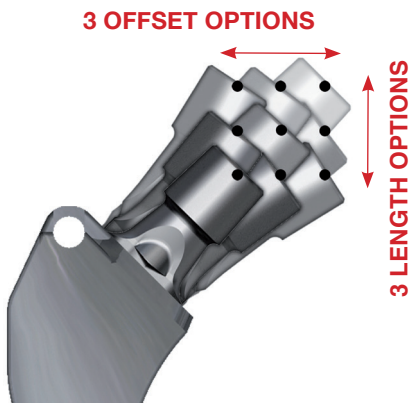
Patients with shorter necks can also achieve a sufficient version correction.

The MODULA® SF system allows for the independent adjustment of the 3 main parameters: Length, Offset, Version.

Changing one of these parameters does not affect the others.

LOGICAL, SIMPLE, COMPLETE.

Logical



MODULA® SF Matrix frontal view the surgeon can select between 3 offset and 3 length options.

MODULA® SF is an exclusive system based on a tridimensional linear square matrix. On the frontal plane the matrix has 9 regularly distributed positions. The surgeon can therefore move independently along the two axes:

- **Vertical** to adjust the length.
- **Horizontal** to adjust the offset.

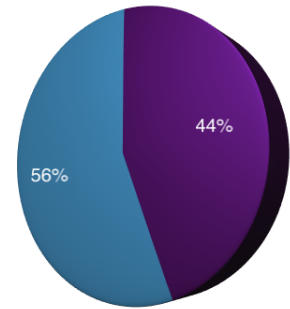
The advantages of the modular system

The system includes 3 “straight” necks with the longitudinal axis aligned to the CCD angle and 12 “tilted” necks that are angled on one or two planes. The type of necks implanted are divided as follows (*):

The “tilted” necks (covering 24 points of the matrix) make up more than half of the implants (56%).

The 3 “straight” necks (covering 3 points of the Matrix) were used in 44% of cases.

● Tilted necks ● Straight necks :



In most cases a “tilted” neck had to be implanted in order to reconstruct the patient anatomy.

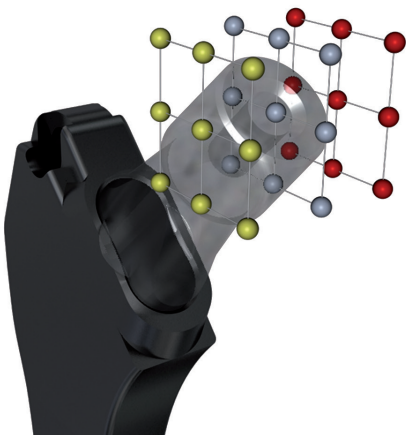
(*) Data related to 40,000 implanted modular necks available from Adler Ortho.

Simple



To help the surgeon in selecting the most suitable neck, the trial necks are positioned on a white plate which faithfully reproduces the square matrix on the frontal plane. Two more plates are used to accommodate the anteverted and retroverted necks.

Complete



The 27 points of the tridimensional matrix are covered with the 15 different necks. By combining the matrix positions with the three head options available, the surgeon has **81 different options** at his disposal to accurately reconstruct the hip joint geometry.



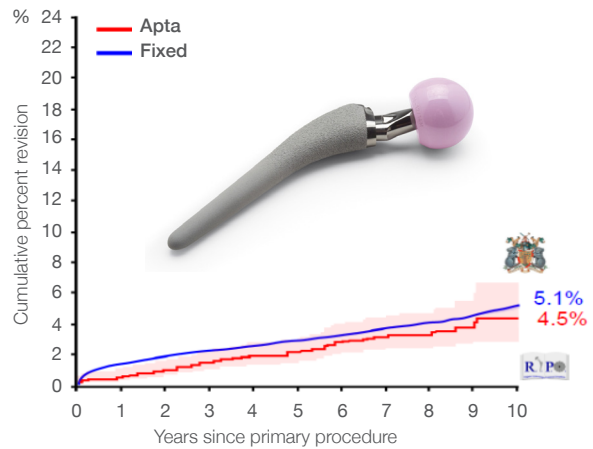
CLINICAL RESULTS

Long Term Follow Up

When properly designed and manufactured modular stems show long term survival rates comparable or better than monolithic ones (*).

(* Sources: R.I.P.O. Registry 2014 Report and the Australian National Joint Registry 2015 Report

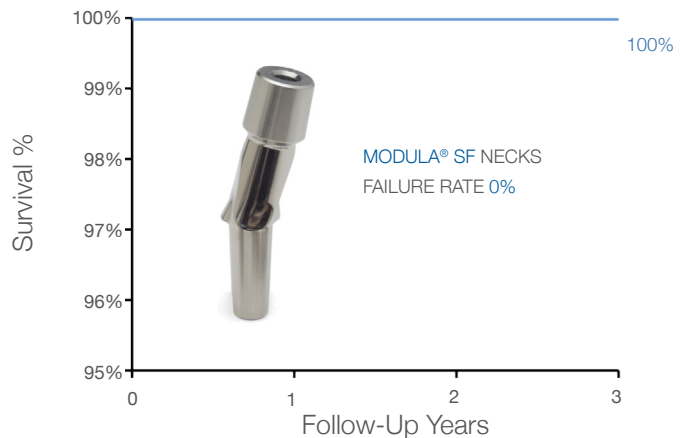
Apta stem with MODULA® SF Necks Vs Fixed Neck Stems
10 Years Survival rate



Outstanding Reliability

MODULA® SF Necks, introduced in the year 2012, show no failures at 3 years coupled with the very low dislocation rate of 0.4%. (*)

(* Source: R.I.P.O. Registry 2014 Report



- 40,000** MODULA® SF Necks implanted in the 2012-2015 period
- 1,873** MODULA® SF Necks included in the RIPO Registry (*).
- 0** Failures observed (*).
- 0.4%** Dislocation rate observed in the cohort.

(* Source: R.I.P.O. Registry 2014 Report

MODULA® SF Necks Reliable and Clinically Proven

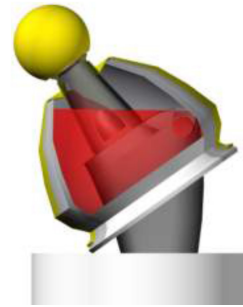
Why Titanium?

Titanium Alloy is the most suitable material for cementless stems. Modular necks can be made of titanium alloy or of Co-Cr-Mo alloy.

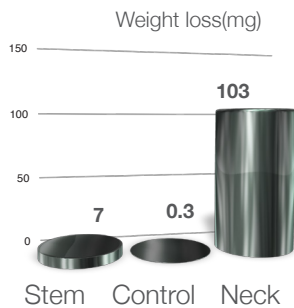
The coupling of two different metal alloys (Ti-6Al-4V and Co-Cr-Mo) has been associated with corrosion issues and the release of big quantities of metal ions. (15;16;17;18;19,21,22)

Laboratory Tests

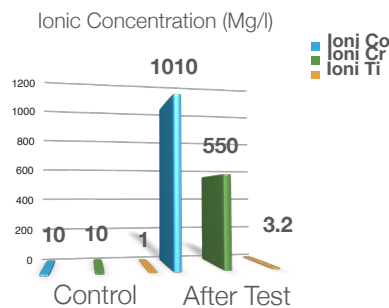
A number of Co-Cr-Mo necks were assembled on titanium stems and submitted to 5 million load cycles according to ISO 7206/4. The neck area was maintained in a ferric chloride solution (FeCl3) according to ASTM G48-03. As a reference one of the samples was kept in the solution without load.



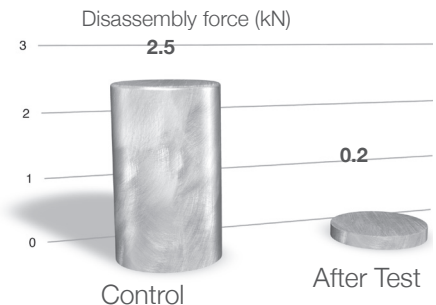
Results



After the test the CoCr neck lost 103 mg. There was practically no variation in the control neck weight.



After the test we found a significant increase in the concentration of Co and Cr ions in the Ferric Chlorine solution.



After the test the force needed to disassemble the neck decreased 10 times.

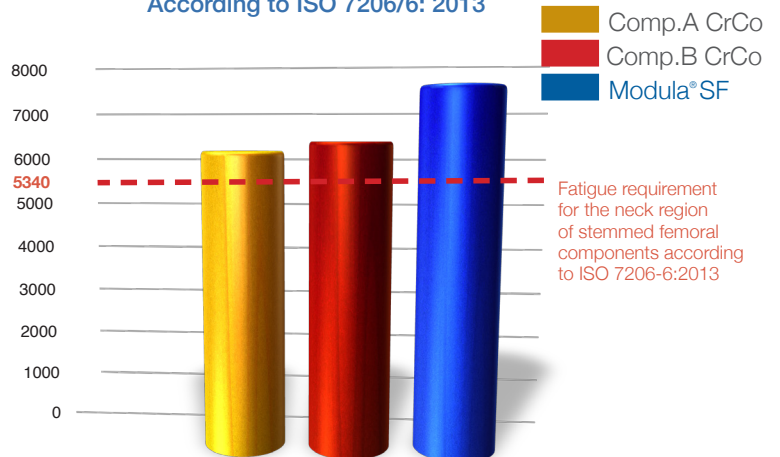
The titanium alloy/titanium alloy coupling does not present corrosion issues, but it can be sensitive to fretting issues that could undermine its mechanical performance. (23)

However by:

- Optimizing the coupling length.
- Submitting the male taper surface to an exclusive surface finish.
- Optimizing the shape and surface finish of the female taper.
- Optimizing the coupling clearance.

We achieved a very high mechanical strength for the MODULA® SF necks.

Necks Fatigue resistance at 10 million cycles. According to ISO 7206/6: 2013



Titanium alloy MODULA® SF necks are more reliable and guarantee long lasting coupling.

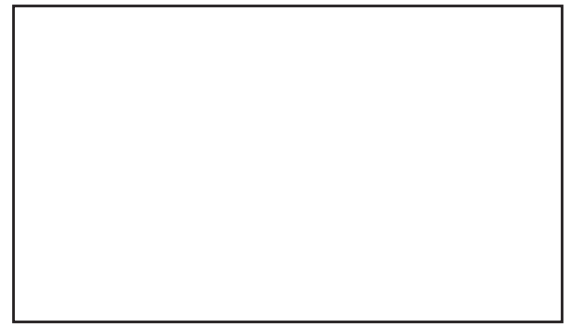
Surgeon should carefully evaluate the use of modular necks with high frontal offset and/or anteversion or retroversion in heavy patients and/or performing high impact sporting and/or physical demanding working activities, because the risk of early complications could be higher than normal.



Adler Ortho SpA
Via dell'Innovazione 9
20032 Cormano, Italy
Tel +39 02 6154371
Fax +39 02 615437222
www.adlerortho.com

Adler Ortho UK
The Stables
Tarvin Road
Frodsham - Cheshire -
WA6 6XN
Tel: +44151 329 3372

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Manufactured by Adler Ortho  0426

Modula®SF neck is protected by the following patents:



European Patent EP 1 635 742 B1
US Patent 7,588,602 B2
European Patent EP 1 663 077 B